



Brand Name : ALUCID TABLETS	
Generic Name : Aluminium Hydroxide Tablets BP 500 mg	2021
Module 1	Administrative Information and Product Information
1.5	Product Information Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

ALUCID TABLETS
(Aluminium Hydroxide Tablets BP 500 mg)

2. Qualitative and Quantitative Composition:

Each Chewable tablet contains: Aluminium Hydroxide BP 500 mg

3. Pharmaceutical form:

Light yellow coloured, circular, flat, bevelled edge, chewable tablet having a breakline on one side of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

Aluminum is a naturally occurring mineral. Aluminum hydroxide is an antacid.

Aluminum hydroxide is used to treat heartburn, upset stomach, sour stomach, or acid indigestion. Aluminum hydroxide is also used to reduce phosphate levels in people with certain kidney conditions.

Aluminum hydroxide may also be used for purposes not listed in this medication guide.

Dietary phosphorus restriction, oral administration of phosphorus binders, and dialysis are the main strategies to control hyperphosphatemia in patients with stage 5 chronic kidney disease. Aluminum hydroxide (AH) and calcium carbonate, the most



commonly used phosphorus binders, have serious disadvantages, such as aluminum toxicity and hypercalcemia. Sevelamer hydrochloride (SH) is a relatively new nonabsorbed calcium- and aluminum-free phosphorus binder. The present study was designed to evaluate the efficacy of SH in the control of hyperphosphatemia and its effect, compared to AH, on serum lipid parameters in patients on continuous ambulatory peritoneal dialysis (CAPD). 30 stable patients on CAPD were included in an open-label, randomized crossover study. After a 2-week phosphorus binder washout period, 15 patients (group I) were administered SH for 8 weeks and in the remaining patients (group II), AH was introduced (phase A). After a new 2-week washout period, patients crossed over to the alternate agent for another 8 weeks (phase B). There were similar reductions in serum phosphorus levels over the course of the study with both agents: by 1.18 +/- 0.07 mg/dL (0.38 +/- 0.03 mmol/L) with SH and by 1.25 +/- 0.15 mg/dL (0.40 +/- 0.05 mmol/L) with AH in phase A (p = NS), and by 1.35 +/- 0.25 mg/dL (0.43 +/- 0.08 mmol/L) with AH and by 1.23 +/- 0.80 mg/dL (0.39 +/- 0.25 mmol/L) with SH in phase B (p = NS). Moreover, SH administration was associated with a 10.5% +/- 9.4% and a 20.1% +/- 6.8% fall in total cholesterol (p < 0.05) and low-density Lipoprotein cholesterol (p < 0.001) in phase A, and 11.9% +/- 7.2% (p < 0.05) and 21.5% +/- 2.4% (p < 0.001), respectively, in phase B. In both phases of the study, AH administration was not followed by a significant change in serum lipid parameters. Sevelamer hydrochloride is a well-tolerated alternative to calcium- or aluminum-containing phosphorus binder in the control of serum phosphorus in CAPD patients. Furthermore, SH improves the lipid profile in these patients.

4.2 Posology and Method of Administration:

1-2 tablets chewd 4 times daily and at bedtime or as required.

Method of administration : Oral.

4.3 Contraindications:

- Hypersensitivity to aluminum salts

4.4 Special Warnings and Precautions for Use :

- Aluminum toxicity may occur in renal failure patients.
- Low blood phosphate levels (hypophosphatemia) may occur.
- Use caution in patients with heart failure, cirrhosis, edema, or renal failure.
- Will bind calcium if given at same time.
- Elderly may be predisposed to fecal impaction.
- Use caution in patients who have recently suffered massive gastrointestinal hemorrhage.



4.5 Interaction with other medicinal products, and other forms of interaction:

If your doctor has directed you to use this medication, your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor, health care provider or pharmacist first.

Severe interactions of aluminum hydroxide include:

- pazopanib
- raltegravir

Aluminum Hydroxide has serious interactions with at least 26 different drugs.

Aluminum Hydroxide has moderate interactions with at least 108 different drugs.

Mild interactions of aluminum hydroxide include:

- ascorbic acid
- aspirin
- aspirin rectal
- aspirin/citric acid/sodium bicarbonate
- balsalazide
- blessed thistle
- choline magnesium trisalicylate
- chromium
- devil's claw
- diflunisal
- mesalamine
- rose hips
- salicylates (non-ASA)
- salsalate
- strontium ranelate
- sucralfate
- sulfasalazine
- willow bark

This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist. Check with your physician if you have health questions or concerns.



4.6 Pregnancy and Lactation:

- Use aluminum hydroxide with caution during pregnancy if benefits outweigh risks. Animal studies show risk and human studies are not available or neither animal nor human studies were done.
- It is not known whether aluminum hydroxide is excreted in breast_milk. Consult your doctor.

4.9 Overdose:

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

Overdose symptoms may include severe constipation, weight loss, confusion, mood changes, or urinating less than usual or not at all.

5. Pharmaceutical particulars:

5.1 List of Excipients:

Sucrose	BP
Sodium Sachharin	BP
Sodium methyl paraben	BP
Sodium propyl paraben	BP
Gelatin	BP
Colour Tartrazine supra	INH
Maize starch	BP
Purified talc	BP
Magnesium stearate	BP
Peppermint oil	BP

5.2 Incompatibilities:

None Reported

5.3 Shelf-Life:

36 months from the date of manufacture.

5.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.



5.5 Nature and Contents of Container:

1000 tablets packed in one Jar. Such jar packed in unit jar along with its package insert. Such jar packed in export worthy shipper.

5.6 Special precautions for disposal:

None reported.

6. Registrant:

AGOG PHARMA LTD.

Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraiпада,
Vasai (E), Dist. Thane,
India.

7. Manufacturer:

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8. Date of revision of the text :